

## PATENT COOPERATION TREATY

## PCT

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 6162PTWO/AG/a	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/EP2004/051641	International filing date (day/month/year) 28.07.2004	Priority date (day/month/year) 30.09.2003	
International Patent Classification (IPC) or national classification and IPC C08G63/00, C08G83/00			
Applicant MEDIOLANUM FARMACEUTICI S.p.A. et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 7 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand  25.07.2005		Date of completion of this report  20.01.2006	
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer  Schlicke, B Telephone No. +31 70 340-1013 	

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/051641

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
    - ☐ international search (under Rules 12.3 and 23.1(b))
    - ☐ publication of the international application (under Rule 12.4)
    - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-20 as originally filed

**Claims, Numbers**

1-49 received on 29.07.2005 with letter of 15.07.2005

**Drawings, Sheets**

1/1 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
    - ☐ the description, pages
    - ☐ the claims, Nos.
    - ☐ the drawings, sheets/figs
    - ☐ the sequence listing (*specify*):
    - ☐ any table(s) related to sequence listing (*specify*):
  4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
    - ☐ the description, pages
    - ☐ the claims, Nos.
    - ☐ the drawings, sheets/figs
    - ☐ the sequence listing (*specify*):
    - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/051641

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	1-49
	No: Claims	
Inventive step (IS)	Yes: Claims	1-49
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-49
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

- 1 Reference is made to the following documents:

D1: US4526938 (IMPERIAL CHEMICAL INDUSTRIES), 02.07.1985

D2: WO-A-03008480 (SAMYANG CORPORATION), 30.01.2003

- 2 Document D1 describes block copolymers comprising hydrophobic polyester segments and hydrophilic polyvinyl pyrrolidone segments (claim 1; example 1).

According to claim 1 and col. 3, lines 29-40 of D1, the copolymers may be linear (AB,BA,ABA and BAB), branched or grafted.

D1 teaches further compositions comprising these block copolymers and a drug (col. 5, lines 45-55).

D1 fails to disclose PVP segments having a weight average molecular weight between 600 and 15000.

Hence, the subject-matter of present claims 1 and 48 appears novel in view of D1 (Article 33(2) PCT).

- 3 The document D2 discloses AB block copolymers comprising hydrophobic polyester segments and hydrophilic segments having a weight average molecular weight of 100 to 100000 Daltons (claims 1,5,9). The hydrophilic segments may be based on polyvinyl pyrrolidone.

D2 fails to disclose a specific embodiment in which the hydrophilic segments are PVP, let alone PVP having a certain preferred molecular weight. Since the selected sub-range is further narrow and not arbitrarily chosen (see page 4, lines 7-15 of the present application), the subject-matter of present claims 1 and 48 appears to be novel in view of D2 (Article 33(3) PCT).

- 4 The available prior art does not give any incentive to select the molecular weight of the PVP segments according to the range of present claim 1. Since such a selection is not obvious to the skilled person, the subject-matter of present claims 1 and 48 appears to involve an inventive step in the sense of Article 33(3) PCT.
- 5 D1 teaches (example 8) a method of preparing PVP and polyester containing segment copolymers by polymerizing vinyl pyrrolidone onto a preformed polyester segment. This clearly differs from the methods according to present process claims 26,31,34,39 and 44, in which the polyester is polycondensated onto a preformed PPV-segment.

Since the available prior art fails to provide any further incentive with regard to the processes according to the present invention, the subject-matter of claims 26,31,34,39 and 44 appears to involve an inventive step in the sense of Article 33(3) PCT.

- 6 The available prior art neither discloses nor fairly suggests the use of PPV and polyester containing segment copolymers for preparing blends with poly(lactic-glycolic) acid. The subject-matter of present claim 49 therefore complies with the requirements of Article 33(1) PCT.